$AF/3761
#22
DL
3-6-03

In the United States Patent and Trademark Office

Appellants:	David J. Tyrrell et al.	Docket No.:	16,496
Serial No.:	09/746,880	Group:	3761
Confirmation No.:	9383	Examiner:	J. Webb
Filed:	December 22, 2000	Date:	February 14, 2003

For: ABSORBENT ARTICLES WITH NON-AQUEOUS COMPOSITIONS CONTAINING ANIONIC POLYMERS

Appeal Brief Transmittal Letter

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192, transmitted herewith in triplicate is an Appeal Brief pursuant to the Notice of Appeal which was mailed on January 8, 2003.

Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(c), which is due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. This Appeal Brief Transmittal Letter is submitted in duplicate.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A Dudkowski
Alyssa A. Dudkowski
Registration No.: 40,596

CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell
Cynthia M. Trudell

In the United States Patent and Trademark Office

Appellants:	David J. Tyrrell et al.	Docket No.:	16,496
Serial No.:	09/746,880	Group:	3761
Confirmation No.:	9383	Examiner:	J. Webb
Filed:	December 22, 2000	Date:	February 14, 2003

For: ABSORBENT ARTICLES WITH NON-AQUEOUS COMPOSITIONS CONTAINING ANIONIC POLYMERS

Brief on Appeal to the Board of Patent Appeals and Interferences

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192 Appellants respectfully submit this Brief in support of their Appeal of the **Final Rejection** of claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 that was mailed on September 25, 2002. On January 8, 2003, Appellant, pursuant to 37 C.F.R. 1.191 mailed a timely Notice of Appeal which was received in the Patent Office on January 14, 2003. In accordance with 37 C.F.R. 1.192(a) this Appeal Brief is filed in triplicate.

Real Party in Interest

Kimberly-Clark Worldwide, Inc., the assignee of the present patent application, is the real party in interest.

Related Appeals and Interferences

Applicants submit that there are two (2) related Appeals: (1) a Notice of Appeal was also mailed for co-pending application serial number 09/746,872 (also filed on December 22, 2000); and (2) a Notice of Appeal was also mailed for co-pending application serial number 09/746,888 (also filed on December 22, 2000). These three applications pertain to the same general subject matter and the grounds of final rejection/arguments in response are similar. Further, all three applications are before the same Examiner, Examiner Jamisue Webb.

Status of the Claims

Claims 1-56 are pending in the application.

Claims 6, 7, 16-19, 30, 31, 36-39, 42, 44 and 48 are withdrawn from consideration.

Claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 stand rejected and form the subject matter of this appeal.

Status of Amendments Filed Subsequent to Final Rejection

An Amendment After Final was submitted on November 21, 2002. By way of an Advisory Action mailed December 26, 2002, the Examiner considered the request for reconsideration but did not find the application to be in condition for allowance.

Summary of the Invention

In one aspect, the present invention is directed to an absorbent article including an outer cover; a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover; and an absorbent body that is located between the bodyside liner and the outer cover. Further, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner. The composition includes: **(1)** from about 40 to about 95 percent by weight of emollient; **(2)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(3)** from about 0.1 to about 20 percent by weight of decoupling polymer. **(See, for example, claim 1)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 40 to about 95 percent by weight of emollient; **(2)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(3)** from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 15)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 0.1 to about 95 percent by weight of natural fats or oils; **(2)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(3)** from about 1 to about 95 percent by weight of emollient; **(4)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer. **(See, for example, claim 20)** In a further aspect of the present invention, the article includes a composition including the same components and where the decoupling polymer is selected from: homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-

sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 35)**.

In another aspect, the present invention is directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method includes a step of heating a composition to a temperature above the melting point of the composition, where the composition includes: **(1)** emollient; **(2)** viscosity enhancer; and **(3)** decoupling polymer. The composition has a melting point of from about 32°C to about 100°C. The method also includes the steps of applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article and resolidifying the composition. **(See, for example, claim 40)**

In another aspect, the present invention is directed to a method for protecting the skin barrier on a skin surface of a user. The method includes a step of contacting the skin surface of the user with a bodyfacing surface of a liner material. The bodyfacing surface of the liner material includes a composition where the composition includes an emollient, a viscosity enhancer and a decoupling polymer. The method also inlcudes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface. The method further includes a step of repeating contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to protect the skin barrier. More specifically, the composition on the liner material includes: **(1)** from about 1 to about 95 percent by weight of emollientt; **(2)** from about 1 to about 40 percent by weight of viscosity enhancer; and **(3)** from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 53)**

The Issues Presented

In the First Office Action mailed March 27, 2002, the Examiner rejects claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,294,186 issued to Beerse et al. (hereinafter "the Beerse patent").

The Examiner believes the Krzysik patent discloses an absorbent article including a topsheet, a backsheet and an absorbent core located in between the topsheet and the backsheet. (See Appendix B for portions of the Krzysik patent cited by the Examiner). The Examiner believes the Krzysik patent discloses a lotion composition on the topsheet where the lotion composition is melted, applied to the

topsheet and then cooled. The Examiner believes the Krzysik patent discloses a composition comprising 5-95% emollient, 0.1-25% of a viscosity enhancer and 5-95% of a wax, which can be a natural oil such as hydrogenated cottonseed oil. The Examiner acknowledges that the Krzysik patent does not disclose a lotion composition including a sterol and a decoupling polymer.

The Examiner believes the Beerse patent discloses the use of a lotion composition that can be used on diapers, is based on an emollient and that contains about 0.1 to 10% of a decoupling polymer such as polysaccharides or polyacrylamides, a clay and a skin moisturizer such as sterol cholesterol present from 0.1 to 20%. (See Appendix C for portions of the Beerse patent cited by the Examiner) The Examiner believes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of the Krzysik patent to include the decoupling agent, clay and sterol of the Beerse patent in order to thicken the skin care composition to improve the moisturizing effect of the composition.

In the Appellants's response mailed July 15, 2002, Appellants respond to the Examiner's rejection of the claims over the combination of the Krzysik and Beerse patents.

In the Final Office Action mailed September 25, 2002, the Examiner indicates that she did not find the Appellants's arguments of July 15, 2002 to be persuasive. In response to Appellants' argument that the Examiner has not identified why one of ordinary skill in the art would be motivated to add the thickening agents and skin moisturizing agents of the Beerse patent in view of the large number of groups of compounds disclosed in the Beerse patent, the Examiner believes the Beerse patent gives a reason in column 10 to add the thickening agent and the moisturizing agent to a lotion composition. Therefore, the Examiner believes the motivation to combine the two references is in the Beerse patent. In response to Appellants' argument that no motivation is identified to picking elements from the Beerse patent, the Examiner believes the Beerse patent provides motivation to add a skin moisturizing agent into the composition. The Examiner believes the Beerse patent provides a list of suitable materials that can be used for the skin moisturizing agents, therefore disclosing that a suitable skin moisturizing agent is a sterol, such as cholesterol. The Examiner was not persuaded by Appellants' arguments that it would be undesirable to use an antibacterial composition on the bodyside liner (a.k.a. topsheet) of a diaper. The Examiner indicated that a subclass of art has been devoted to the use of antibacterial material on topsheets or in contact with a user's skin in diapers or other absorbent articles. With respect to Appellants' method claims, the Examiner believes the Krzysik patent discloses lotion being located on the topsheet, and while the article is being worn, the lotion is transferred to the skin of the wearer, therefore causing a layer of protection; the Examiner considers this to be a method of protecting the skin.

In the Advisory Action mailed December 26, 2002, the Examiner indicates that she believes the conclusion of obviousness is not based upon improper hindsight reasoning. The Examiner explains that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. The Examiner also explains that so long as the reasoning takes into account only knowledge that was within the level of ordinary skill at the time the invention was made and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. With respect to Appellants' argument that the Beerse patent does not provide motivation for selecting the polysaccharides/polyacrylamide polymers from the long list provided in the Beerse patent, the Examiner believes the Krzysik patent discloses a lotion. The Examiner also believes the Beerse patent discloses a lotion composition with an additional skin moisturizing component. The Examiner believes the Beerse patent provides the motivation to add the moisturizing component to the Krzysik patent and that the motivation to combine comes from adding the skin moisturizing component to the Krzysik patent lotions. The Examiner believes the Beerse patent then names a list of suitable moisturizing components (that the Examiner considers capable of acting as a thickening agent) which include the polysaccharide/polyacrylamide. With respect to Appellants' arguments that the Beerse patent does not provide motivation to put the thickening agent in a lotion, the Examiner believes the Beerse patent discloses a composition being used in lotions and wipes and therefore, a motivation to combine exists.

1. Whether claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 are unpatentable under 35 U.S.C. § 103 over the Krzysik patent in view of the Beerse patent?

A. Specifically, has the Examiner met the burden of establishing a *prima facie* case of obviousness?

1. Has the Examiner met the burden of establishing that there is a suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references and to combine the teachings of the references?

i. Claim Group I: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 40 to about 95 percent by weight of emollient; **(2)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(3)** from about 0.1 to about 20 percent by weight of decoupling polymer?

ii. Claim Group II: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the

references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 0.1 to about 95 percent by weight of natural fats or oils; **(2)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(3)** from about 1 to about 95 percent by weight of emollient; **(4)** from about 0.1 to about 40 percent by weight of viscosity enhancer; **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer?

2. Has the Examiner met the burden of establishing that there would be a reasonable expectation of success? (Claim Groups I and II)

Grouping of the Claims

For the rejections described in Issue 1:

Group I: Claims 1-5, 8-15, 40, 41, 43, 45-47 and 49-56 stand or fall as a group.

Group II: Claims 20-29 and 32-35 stand or fall as a group.

The rejected claims do not stand or fall together. The claims should be considered in two groups for the reasons provided in the Argument section below.

Argument

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Krzysik patent for modifying its teachings with the teachings of the Beerse patent.

Claim Group I: Claims 1-5, 8-15, 40, 41, 43, 45-47 and 49-56 are directed, in part, to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 40 to about 95 percent by weight of emollient; **(2)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(3)** from about 0.1 to about 20 percent by weight of decoupling polymer. Neither of the two cited references (the Krzysik patent and the Beerse patent) discloses the claimed composition applied to a bodyside liner of an absorbent article. The Examiner improperly "picked and choosed" the components from the two references using the claimed invention as a template in order to form the rejection.

In the First Office Action mailed March 27, 2002, the Examiner states "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Krzysik to include the decoupling agent, clay and sterol of Beerse, in order to thicken the skin care composition to improve the moisturizing effect of the composition." In the Final Office Action mailed September 25, 2002, the Examiner states "Beerse gives a reason in column 10 to add the thickening agent and the moisturizing agent to a lotion composition, therefore the motivation to combine the two references is in the Beerse patent" and "Beerse provides motivation to add a skin moisturizing agent into the composition, the Beerse reference then provides a list of suitable materials that can be used for the skin moisturizing agents, therefore disclosing that a suitable skin moisturizing agent is a sterol, such as cholesterol." In the Advisory Action mailed December 26, 2002, the Examiner states "The Krzysik patent discloses a lotion, the Beerse patent discloses a lotion composition with an additional skin moisturizing component. Beerse provides the motivation to add the moisturizing component to the Krzysik patent." The Examiner also states "The motivation to combine comes rom [sic] adding the skin moisturizing component to Krzysik. Beerse then names a list of suitable moisturizing componets [sic] ... which include the polysaccharide/polyacrylamide." The Examiner further states "Beerse, in column 4, lines 3-4 disclose the composition being used in lotions and wipes, therefore there exist [sic] a motivation to combine." In the First Office Action, the Final Office Action and the Advisory Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The Examiner does not adequately state why one of ordinary skill would read the Krzysik patent and then look to the Beerse patent to select additional particular compounds to arrive at the composition of claims 1-5, 8-15, 40, 41, 43, 45-47 and 49-56.

Claim Group I includes claims directed, in part, to absorbent articles with compositions including three components: (1) emollient; (2) viscosity enhancer; and (3) decoupling polymer. The Krzysik patent discloses an absorbent article having a lotionized bodyside liner, but as acknowledged by the Examiner, the Krzysik patent does not disclose a lotion composition that includes a decoupling polymer. (See Office Action mailed March 27, 2002, page 5). In order to show "disclosure" of a decoupling polymer, the Examiner relies on the Beerse patent which is directed to antimicrobial compositions including a benzoic acid analog and a metal salt. The Examiner believes the Beerse patent discloses the decoupling polymers of the present invention at Col. 36, line 51 to Col. 37, line 46 (polysaccharides or polyacrylamides). (See Appendix C to this Appeal Brief for this portion of the Beerse patent.)

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner believes that one

of skill in the art would look to column 10 of the Beerse patent for disclosure of "lipophilic skin moisturizing agents/emollients", select polysaccharides/polyacrylamides and know to add them to the lotion compositions of the Krzysik patent . There are several reasons why this proposed "motivation" is not logical and not sufficient. First, in the Advisory Action mailed December 26, 2002, the Examiner states "Beerse then names a list of suitable moisturizing componets [sic] ... which include the polysaccharide/polyacrylamide." Appellants assert that the Examiner is mistaken. Neither polysaccharides nor polyacrylamides are identified as "skin moisturizing agents" in column 11 of the Beerse patent. Second, Col. 11, lines 43-45 of the Beerse patent do state: "Lipophilic skin moisturizing agents/temollients [sic] may also be incorporated into the water or alcohol based solutions or gels" (emphasis added). The compositions of the present invention are nonaqueous; the Beerse patent is directed water or alcohol based solutions. One of skill in the art would not look to the Beerse patent for possible components of nonaqueous compositions. Third, at Col. 11, lines 7-10, the Beerse patent does state "Also useful herein are hydrophilic gelling agents such as the acrylic acid/ethyl acrylate copolymers." However, the Beerse patent identifies "hydrophilic gelling agents" as "thickeners [that] can be be added to the water or alcohol based solutions of the present invention to form a gel." (See Col. 9, lines 55-56 of the Beerse patent). Again, the Examiner has not explained why one would look at components identified for the water based solutions of the Beerse patent and be motivated to use them in the nonaqueous compositions of the Krzysik patent.

Additionally, one of skill in the art could not simply apply the compositions of the Beerse patent to a diaper to arrive at the claimed invention. The Examiner had to select polysaccharides/polyacrylamides from thousands of compounds disclosed as possible components of the antimicrobial compositions of the Beerse patent. Further, while the Beerse patent identifies "diapers" as a suitable "carrier" (at Col. 9, line 12), the Beerse patent also identifies many other suitable "carriers" and "product forms" that are very different from diapers (e.g. dental floss, chewing gum, toothpaste etc. at Col. 9, lines 9-27). Additionally, the Beerse patent does not provide any guidance or examples for formulating compositions of the Beerse patent for use on diapers. The Examiner has failed to identify how the cited reference suggests the desirability of modifying the compositions of the Krzysik patent to include components from the Beerse patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of the compositions of Claim Group I from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir.

1988)[1]. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group I are separately patentable over the references.

Claim Group II: Claims 20-29 and 32-35 are directed to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 0.1 to about 95 percent by weight of natural fats or oils; **(2)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(3)** from about 1 to about 95 percent by weight of emollient; **(4)** from about 0.1 to about 40 percent by weight of viscosity enhancer; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer. As compared to Claim Group I, the compositions of Claim Group II include the additional components of natural fats or oils and sterols or sterol derivatives. The Examiner believes the Krzysik patent discloses natural fats or oils (at Col. 10, line 24) and the Examiner believes the Beerse patent discloses sterols or sterol derivatives (at Col. 10, line 43 to Col. 11, line 16). However, for the same reasons as those stated above, the Examiner does not identify how the references suggest the desirability of modifying the Krzysik patent compositions to include these additional components from the Beerse patent. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group II are separately patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the compositions of the Krzysik patent to include components from the Beerse patent.

One of the benefits of the compositions of the present invention is their ability to reduce the irritation response of the skin when the skin is exposed to fecal protease and bile acid insults. (See pages 62-70 of the Specification as filed; copy provided as Appendix D to this Appeal Brief). In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor of reducing the irritation response of skin exposed to fecal proteases and bile acids. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success at reducing irritation response. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

---

[1] "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that

The Beerse patent relates to antimicrobial compositions that provide immediate as well as residual anti-viral and antibacterial efficacy. (See Col. 1, lines 44-46). The Examiner does not explain why one of skill in the art would have been motivated to select the "skin moisturizing agents" and the "thickening agents" of the Beerse patent to be used in the lotion compositions of the Krzysik patent- particularly in view of the large number of groups of compounds disclosed in the Beerse patent- for the purpose of reducing skin irritation response to fecal proteases and bile acids. Therefore, there would have been no expectation of success at arriving at a composition that reduces the irritation response of skin to the enzymes in biological fluids as occurs with the compositions claimed by the present invention. Additionally, none of the cited references recognize the "result-effective" capability of the decoupling polymers of the present invention.

In view of the above Arguments, it is respectfully submitted that the rejection of claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 under 35 U.S.C. § 103 are in error. Accordingly, Appellants respectfully request that the Examiner's rejection be reversed. Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(f), for filing this Appeal Brief to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. Any additional prosecutional fees which are due may also be charged to deposit account number 11-0875.

The undersigned may be reached at: (920) 721-2433.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A. Dudkowski

Alyssa A. Dudkowski
Registration No.: 40,596

CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell

Cynthia M. Trudell

---

the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

Appendix A – The Claims On Appeal

1. An absorbent article comprising:

   (a) an outer cover;

   (b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

   (c) an absorbent body that is located between the bodyside liner and the outer cover; and

   (d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 40 to about 95 percent by weight of emollient, from about 0.1 to about 40 percent by weight of viscosity enhancer and from about 0.1 to about 20 percent by weight of decoupling polymer.

2. The absorbent article of claim 1, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

3. The absorbent article of claim 1, wherein the emollient of the composition is selected from petrolatum, vegetable based oils, mineral oils, dimethicone, lanolin, glycerol esters, alkoxylated carboxylic acids, alkoxylated alcohols, fatty alcohols and mixtures thereof.

4. The absorbent article of claim 1, wherein the viscosity enhancer of the composition is selected from polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, organically modified clays, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose, microcrystalline wax, shellac wax, hexadecyl cosanyl hexacosanate, C_{20}-C_{40} alkyl hydroxystearyl stearate, glycol montanate, ozokerite wax, polyperfluoromethylisopropylether montan wax and mixtures thereof.

5. The absorbent article of claim 1, wherein the decoupling polymer of the composition is selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

6. (Withdrawn)

7. (Withdrawn)

8. The absorbent article of claim 1 wherein the composition further includes from about 0.1 to about 59 percent by weight of natural fats or oils.

9. The absorbent article of claim 8, wherein the natural fat or oil is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

10. The absorbent article of claim 1 wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives.

11. The absorbent article of claim 10, wherein the sterol or sterol derivative is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C_{10}-C_{30} cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

12. The absorbent article of claim 1, wherein the composition further includes from about 0.5 to about 20 percent by weight of a rheology modifier.

13. The absorbent article of claim 12, wherein the rheology modifier is selected from silica, silica silylate, silica methyl silylate, quaternary starch compounds, quaternary modified clays, organically modified clays and mixtures thereof.

14. The absorbent article of claim 13, wherein the composition further comprises from about 1 to about 20 by weight of clay selected from natural clays and synthetic analogs of natural clays.

15. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 40 to about 95 percent by weight of emollient, from about 0.1 to about 40 percent by weight of viscosity enhancer and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

16. (Withdrawn)

17. (Withdrawn)

18. (Withdrawn)

19. (Withdrawn)

20. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 0.1 to about 95 percent by weight of natural fats or oils, from about 0.1 to

about 10 percent by weight of sterols or sterol derivatives, from about 1 to about 95 percent by weight of emollient, from about 0.1 to about 40 percent by weight of viscosity enhancer and from about 0.1 to about 20 percent by weight of decoupling polymer.

21. The absorbent article of claim 20, wherein the composition has a melting point from about 32°C to about 100°C.

22. The absorbent article of claim 20, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

23. The absorbent article of claim 20, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

24. The absorbent article of claim 20, wherein the composition is on the bodyfacing surface in an amount of from about 0.1 grams per meter squared (g/m2) to about 30 g/m2.

25. The absorbent article of claim 20, wherein the natural fat or oil of the composition is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

26. The absorbent article of claim 20, wherein the sterol or sterol derivative of the composition is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C_{10}-C_{30} cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

27. The absorbent article of claim 20, wherein the emollient of the composition is selected from petrolatum, vegetable based oils, mineral oils, dimethicone, lanolin, glycerol esters, alkoxylated carboxylic acids, alkoxylated alcohols, fatty alcohols and mixtures thereof.

28. The absorbent article of claim 20, wherein the viscosity enhancer of the composition is selected from polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, organically modified clays, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose, microcrystalline wax, shellac wax, hexadecyl cosanyl hexacosanate, C_{20}-C_{40} alkyl hydroxystearyl stearate, glycol montanate, ozokerite wax, polyperfluoromethylisopropylether montan wax and mixtures thereof.

29. The absorbent article of claim 20, wherein the decoupling polymer of the composition is selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

30. (Withdrawn)

31. (Withdrawn)

32. The absorbent article of claim 20, wherein the composition further includes from about 0.5 to about 20 percent by weight of a rheology modifier.

33. The absorbent article of claim 32, wherein the rheology modifier is selected from silica, silica silylate, silica methyl silylate, quaternary starch compounds, quaternary modified clays, organically modified clays and mixtures thereof.

34. The absorbent article of claim 32 wherein the composition further comprises from about 1 to about 20 percent by weight of a clay selected from natural clays and synthetic analogs of natural clays.

35. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 0.1 to about 95 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 1 to about 95 percent by weight of emollient, from about 0.1 to about 40 percent by weight of viscosity enhancer and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

36. (Withdrawn)

37. (Withdrawn)

38. (Withdrawn)

39. (Withdrawn)

40. A method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article comprising the steps of:

(a) heating a composition comprising an emollient, a viscosity enhancer and a decoupling polymer, to a temperature above the melting point of the composition, the composition having a melting point of from about 32°C to about 100°C;

(b) applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article; and

(c) resolidifying the composition.

41. The method of claim 40, wherein after the step of resolidification, the composition has a viscosity of greater than about 50,000 centipoise.

42. (Withdrawn)

43. The method of claim 40, wherein after the step of heating, the composition is applied by slot coating.

44. (Withdrawn)

45. The method of claim 40, wherein the emollient of the composition is from about 5 to about 95 percent by weight of the composition and is selected from petrolatum, vegetable based oils, mineral oils, dimethicone, lanolin, glycerol esters, alkoxylated carboxylic acids, alkoxylated alcohols, fatty alcohols and mixtures thereof.

46. The method of claim 40, wherein the viscosity enhancer of the composition is from about 0.1 to about 40 percent by weight of the composition and is selected from polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, organically modified clays, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose, microcrystalline wax, shellac wax, hexadecyl cosanyl hexacosanate, C20-C40 alkyl hydroxystearyl stearate, glycol montanate, ozokerite wax, polyperfluoromethylisopropylether montan wax and mixtures thereof.

47. The method of claim 40, wherein the decoupling polymer of the composition is from about 1 to about 20 percent by weight of the composition and is selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate, polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

48. (Withdrawn)

49. The method of claim 40 wherein the composition further includes from about 0.1 to about 95 percent by weight of natural fats or oils selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

50. The method of claim 40 wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C_{10}-C_{30} cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

51. The method of claim 40, wherein the composition further includes from about 0.5 to about 20 percent by weight of a rheology modifier selected from silica, silica silylate, silica methyl silylate, quaternary starch compounds, quaternary modified clays, organically modified clays and mixtures thereof.

52. The method of claim 51, wherein the composition further includes from about 1 to about 20 percent by weight of clay selected from natural clays and synthetic analogs of natural clays.

53. A method for protecting the skin barrier on a skin surface of a user, comprising the steps of:

a) contacting the skin surface of the user with a bodyfacing surface of a liner material, the bodyfacing surface having a composition comprising an emollient, a viscosity enhancer and a decoupling polymer;

b) maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface; and

c) repeating the contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to enhance skin barrier function, wherein the composition

comprises from about 1 to about 95 percent by weight of an emollient, from about 1 to about 40 percent by weight of a viscosity enhancer and from about 0.1 to about 20 percent by weight of a decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

54. The method of claim 53, wherein the composition has a melting point from about 32°C. to about 100°C.

55. The method of claim 53, wherein the composition has a viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

56. The method of claim 53, wherein the composition has a penetration hardness of from about 5 to about 365 millimeters at 25°C.

Appendix B

Portions of the Krzysik patent cited by the Examiner as disclosing: "an absorbent article with a topsheet, backsheet and core located there between; the use of a lotioned topsheet to where the lotion composition is melted, applied to the topsheet and then cooled." The Examiner also believes the Krzysik patent discloses: "the composition comprising 5-95% emollient, 0.1-25% of a viscosity enhancer and 5-95% of a wax, which can be a natural oil such as hydrogenated cottonseed oil."

Col. 13, line 64 to Col. 14, line 3:

For example, the lotion formulation may be applied to the bodyside liner **34** by (a) heating the lotion formulation to a temperature above the melting point of the formulation, causing the formulation to melt, (b) uniformly applying the

14

melted formulation to the bodyfacing surface **52** of the bodyside liner **34**; and (c) resolidifying the deposits of the melted formulation. Desirably, resolidification of the deposits occurs almost instantaneously, without the need for external cooling means such as chill rolls. This can occur if the formulation is heated to a temperature only slightly above or at the melting point of the formulation. However,

Abstract:

[57] **ABSTRACT**

An absorbent article having a bodyside liner includes a lotion formulation on the outer bodyfacing surface thereof. The lotion formulation comprises from about 5 to about 95 weight percent of an emollient, from about 5 to about 95 weight percent of a wax, and, optionally, from about 0.1 to about 25 weight percent of a viscosity enhancer. The lotion formulation has a reduced level of migration which leads to improved transfer to the skin. The lotion formulation acts as a lubricant to reduce the abrasion of the skin caused by the liner and also transfers to the skin to provide improved skin health.

Col. 10, line 24:

Suitable waxes which can be incorporated into the lotion formulation include animal, vegetable, mineral or silicone based waxes which may be natural or synthetic such as, for example, bayberry wax, beeswax, C30 alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated jojoba oil, hydrogenated jojoba wax, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, jojoba buffer,

Col. 12, lines 42-58:

The lotion formulation of the present invention may further define a melt point viscosity of from about 50 to about 1000000 centipoise, desirably from about 50000 to about 800000 centipoise, and more desirably from about 100000 to about 500000 centipoise for reduced migration and improved transfer to the skin of the wearer. Lotion formulations which have lower melt point viscosities exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher melt point viscosities may be so solid as to also exhibit a reduced transfer to the skin.

Further, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may also define a viscosity of from about 50 to about 10000 centipoise, desirably from about 100 to about 500 centipoise, and more desirably from about 150 to about 250 centipoise at a temperature of 60° C. Lotion formulations which have lower viscosities at 60° C. exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher viscosities at 60° C. may be so solid as to also exhibit a reduced transfer to the skin.

Col. 9, lines 45-50:

The emollients act as lubricants to reduce the abrasiveness of the bodyside liner to the skin and, upon transfer to the skin, help to maintain the soft, smooth and pliable appearance of the skin. Suitable emollients which can be incorporated into the lotion formulation include oils such as petroleum based oils, vegetable based oils, mineral oils, natural or synthetic oils, silicone oils, lanolin and lanolin derivatives, kaolin and kaolin derivatives and the like and mixtures thereof; esters such as cetyl palmitate, stearyl palmitate, cetyl stearate, isopropyl laurate, isopropyl myristate, isopropyl palmitate and the like and mixtures thereof; glycerol

Col. 10, lines 48-67:

A viscosity enhancer may be added to the lotion formulation to increase the viscosity to help stabilize the formulation on the bodyfacing surface **52** the bodyside liner **34** and thereby reduce migration and improve transfer to the skin. Desirably, the viscosity enhancer increases the viscosity of the lotion formulation by at least about 50 percent, more desirably at least about 100 percent, even more desirably by at least about 500 percent, yet even more desirably by at least about 1000 percent, and even more desirably by at least about 5000 percent. Suitable viscosity enhancers which can be incorporated into the lotion formulation include polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, talc, colloidal silicone dioxide, zinc stearate, cetyl hydroxy ethyl cellulose and other modified celluloses and the like and mixtures thereof. For example, a particularly well suited viscosity enhancer is an ethylene/vinyl acetate copolymer commercially available from E. I. Dupont De Ne Mours, a business having offices located in Wilmington, Del. under the trade designation ELVAX.

Col. 10, lines 19-33:

Suitable waxes which can be incorporated into the lotion formulation include animal, vegetable, mineral or silicone based waxes which may be natural or synthetic such as, for example, bayberry wax, beeswax, C30 alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated jojoba oil, hydrogenated jojoba wax, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, jojoba buffer, jojoba esters, jojoba wax, lanolin wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite, paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, synthetic jojoba wax, synthetic wax, and the like and mixtures thereof. For example, a particularly well suited wax includes about 70 weight percent ceresin wax, about 10 weight percent microcrystalline wax, about 10 weight percent paraffin wax and about 10 weight percent cetyl esters (synthetic spermaceti wax).

Col. 10, line 60 and Col. 11, lines 1-5:

fin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, talc, colloidal silicone dioxide, zinc stearate, cetyl hydroxy ethyl cellulose and

To provide the improved transfer to the skin of the wearer, the lotion formulation may include from about 0.1 to about 25 weight percent, desirably from about 5 to about 20 weight percent, and more desirably from about 10 to about 15 weight percent of the viscosity enhancer for reduced migration and improved transfer to the wearer's skin.

Col. 12, lines 29-34:

Moreover, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may define a melting point of from about 30° C. to about 100° C., desirably from about 35° C. to about 80° C., and more desirably from about 40° C. to about 75° C. Lotion formulations which have lower melting points exhibit migration of the lotion during use and at elevated temperatures in storage which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations

Col. 12, line 66 to Col. 13, line 2:

to also exhibit a reduced transfer to the skin.

The penetration hardness of the lotion formulations of this invention can be from about 5 to about 360 millimeters,

more desirably from about 10 to about 200 millimeters, more desirably from about 20 to about 150 millimeters, and still more desirably from about 40 to about 100 millimeters. (Lotion formulations having a needle penetration hardness greater than 360 millimeters cannot be measured using ASTM method D 1321). The hardness of the lotion formu-

Col. 13, lines 42-55:

desirably at least about 25 percent of the bodyfacing surface of the bodyside liner **34**.

The lotion formulation can be applied to the bodyside liner **34** at any add-on level which provides the desired transfer benefit. For example, the total add-on level of the lotion formulation can be from about 0.05 to about 100 mg/cm^2, desirably from about 1 to about 50 mg/cm^2 and more desirably from about 10 to about 40 mg/cm^2 for improved performance. The add-on amount will depend

Col. 13, line 59:

The lotion formulation may be applied to the bodyside liner **34** in any of many well known manners. A preferred method to uniformly apply the lotion formulation to the surface of the bodyside liner **34** is spraying or slot coating, because it is the most exact process and offers maximum control of the formulation distribution and transfer rate. However, other methods, such as rotogravure or flexographic printing, can be used.

Appendix C

Portions of the Beerse patent cited by the Examiner as disclosing: "a lotion composition that can be used on diapers that contains about 0.1-10% of a decoupling polymer such as polysaccharides or polyacrylamides, a clay and a skin moisturizer such as the sterol cholesterol and is present from 0.1-20%."

Col. 9, lines 12-13:

tion. The cleansing compositions can optionally contain, at their art-established levels, other materials which are conventionally used in cleansing compositions.

Additional carriers suitable for the compositions of the present invention may include various substrate-based products. In such instances, the present compositions may be impregnated into or onto the substrate products and may be allowed to remain wet or may be subjected to a drying process. For instance, suitable carriers include, but are not limited to, dry and wet wipes suitable for personal care and household use (e.g., nonwoven baby wipes, household cleaning wipes, surgical preparation wipes, etc.); diapers; infant changing pads; dental floss; personal care and household care sponges or woven cloths (e.g., washcloths, towels, etc.); tissue-type products (e.g. facial tissue, paper towels, etc.); and disposable garments (e.g., gloves, smocks, surgical masks, infant bibs, socks, shoe inserts, etc.).

Col. 36, line 51 to Col. 37, line 46:

The thickener is preferably present at a concentration of from about 0.01% to about 10%, preferably from about 0.1% to about 5%, and most preferably from about 0.1% to about 3%. Mixtures of the above thickeners may also be used.

Lipophilic skin moisturizing agents/temollients may also be incorporated into the water or alcohol based solutions and gels. Examples of suitable lipophilic skin moisturizers include, but are not limited to, petroleum, mineral oil, micro-crystalline waxes, polyalkenes, paraffin, cerasin, ozokerite, polyethylene, perhydrosqualene, dimethicones, cyclomethicones, alkyl siloxanes, polymethylsiloxanes, methylphenylpolysiloxanes, hydroxylated milk glyceride, castor oil, soy bean oil, maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil, sesame oil, liquid sucrose octaesters, blends of liquid sucrose octaesters and solid polyol polyesters, lanolin oil, lanolin wax, lanolin alcohol, lanolin fatty acid, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate, beeswax, beeswax derivatives, spermaceti, myristyl myristate, stearyl stearate, carnauba and candelilla waxes, cholesterol, cholesterol fatty acid esters and homologs thereof, lecithin and derivatives, Sphingolipids, ceramides, glycosphingo lipids and homologs thereof, and mixtures thereof. A more detailed discussion of useful lipophilic skin moisturizers can be found in U.S. Pat. No. 5,716,920 to Glenn, Jr. et al., issued Feb. 10, 1998, herein incorporated by reference in its entirety.

Also useful as a lipophilic skin moisturizing agent are liquid nondigestible oils such as those described in U.S. Pat. Nos. 3,600,186 to Mattson; Issued Aug. 17, 1971 and 4,005,195 and 4,005,196 to Jandacek et al; both issued Jan. 25, 1977, all of which are herein incorporated by reference, or blends of liquid digestible or nondigestible oils with solid polyol polyesters such as those described in U.S. Pat. No. 4,797,300 to Jandacek; issued Jan. 10, 1989; U.S. Pat. Nos. 5,306,514, 5,306,516 and 5,306,515 to Letton; all issued Apr. 26, 1994, all of which are incorporated by reference herein in their entireties.

When incorporated into the solutions or gels, the lipophilic skin moisturizer is present at concentrations of from about 0.1% to about 20%, preferably from about 1% to about 15%, more preferably from about 2% to about 10% by weight.

Col. 11, line 24:

Optionally, the lipophilic skin moisturizing agent can also be thickened using a thickening agent. Suitable thickening agents for the lipophilic skin moisturizing agent include polacrylates; fumed silica natural and synthetic waxes, alkyl silicone waxes such as behenyl silicone wax; aluminum silicate; lanolin derivatives such as lanesterol; higher fatty alcohols; polyethylenecopolymers; narogel; polyammonium stearate; sucrose esters; hydrophobic clays; petroleum; hydrotalcites; and mixtures thereof.

Col. 10, line 43 to Col. 11, line 16:

The thickener is preferably present at a concentration of from about 0.01% to about 10%, preferably from about 0.1% to about 5%, and most preferably from about 0.1% to about 3%. Mixtures of the above thickeners may also be used.

Lipophilic skin moisturizing agents/temollients may also be incorporated into the water or alcohol based solutions and gels. Examples of suitable lipophilic skin moisturizers include, but are not limited to, petroleum, mineral oil, micro-crystalline waxes, polyalkenes, paraffin, cerasin, ozokerite, polyethylene, perhydrosqualene, dimethicones, cyclomethicones, alkyl siloxanes, polymethylsiloxanes, methylphenylpolysiloxanes, hydroxylated milk glyceride, castor oil, soy bean oil, maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil, sesame oil, liquid sucrose octaesters, blends of liquid sucrose octaesters and solid polyol polyesters, lanolin oil, lanolin wax, lanolin alcohol, lanolin fatty acid, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate, beeswax, beeswax derivatives, spermaceti, myristyl myristate, stearyl stearate, carnauba and candelilla waxes, cholesterol, cholesterol fatty acid esters and homologs thereof, lecithin and derivatives, Sphingolipids, ceramides, glycosphingo lipids and homologs thereof, and mixtures thereof. A more detailed discussion of useful lipophilic skin moisturizers can be found in U.S. Pat. No. 5,716,920 to Glenn, Jr. et al., issued Feb. 10, 1998, herein incorporated by reference in its entirety.

Also useful as a lipophilic skin moisturizing agent are liquid nondigestible oils such as those described in U.S. Pat. Nos. 3,600,186 to Mattson; Issued Aug. 17, 1971 and 4,005,195 and 4,005,196 to Jandacek et al; both issued Jan. 25, 1977, all of which are herein incorporated by reference, or blends of liquid digestible or nondigestible oils with solid polyol polyesters such as those described in U.S. Pat. No. 4,797,300 to Jandacek; issued Jan. 10, 1989; U.S. Pat. Nos. 5,306,514, 5,306,516 and 5,306,515 to Letton; all issued Apr. 26, 1994, all of which are incorporated by reference herein in their entireties.

When incorporated into the solutions or gels, the lipophilic skin moisturizer is present at concentrations of from about 0.1% to about 20%, preferably from about 1% to about 15%, more preferably from about 2% to about 10% by weight.

Appendix D – Pages 62-70 of the Specification as filed.

Cholesterol	--	3%	--	--
AVOCADIN extract	--	--	5.00%	10%
PROLIPID 141 Blend	2%	1%	--	--
Glyceryl Stearate SE	--	--	3%	2%
BENTONE TN Organically Modified Clay	10%	15%	--	--
Silica	--	--	4%	2%
NARLEX DC-1 polymer	3%	--	--	2%
ACULYN R-33 polymer	--	5%	--	--
RHEOTHIX 80-11 polymer	--	--	2%	6%

The decoupling polymers are available from numerous suppliers. For example, NARLEX DC-1 polymer is available from National Starch and Chemical Co. ACULYN R-33 polymer is available from Rohm & Haas company. RHEOTHIK 80-11 polymer is available from Cognis Corporation.

As used herein, all recited ranges of amounts, temperatures, molecular weights and penetration hardnesses are intended to include all sub-ranges within the recited ranges, even though not specifically stated. The following examples are presented to provide a more detailed understanding of the invention.

In order to evaluate the efficacy of the compositions of the invention, a human skin culture was selected to model the response of the human epidermis. EPIDERM skin culture is a cornified, air-interfaced human skin culture. EPIDERM skin culture has multiple layers of progressively differentiated keratinocytes resembling human epidermis. EPIDERM EPI-200 skin culture can be purchased from MatTek Corporation of Ashland, MA. Experiments using EPIDERM skin culture are conducted in six well plates. Typically, five EPIDERM skin culture inserts are added to five of the six wells. Each well contains one milliliter of pre-warmed media that is the same as the EPIDERM skin culture media. The plates are then incubated in a 37°C, 5% CO_2 incubator for thirty minutes. After incubation, 15 microliters of test composition or control are applied to the surface of the EPIDERM skin culture after removing any residual media. For test compositions using a petrolatum base, the composition is applied using a positive-displacement pipettor and spread over the skin culture surface using a glass rod. The well plates, with the test compositions/control applied, are incubated in the 37°C, 5% CO_2 incubator for thirty minutes after which the underlying media is removed and replaced with fresh, pre-warmed media. Next, ten microliters of insult solution, either fecal protease or bile acid, are applied to the surface of the EPIDERM skin culture.

Infant feces contain proteases that include trypsin and chymotrypsin (See Haverback, B. J., Dyce, B.J., Gutentag, P.J., and Montgomery, D. W. (1963) Measurement of Trypsin and Chymotrypsin in Stool. Gasteroenterology 44:588-597; and Barbero, G.J., Sibinga, M.S., Marino, J. M., and Seibel, R. (1966) Stool Trypsin and

Chymotrypsin. Amer. J. Dis. Child 112:536-540). For internal studies, infant feces were collected and the amount of total protease and trypsin activities determined for each of the fecal extracts. To prepare the extract, the feces were suspended in water and vigorously vortexed. After vortexing, the samples were held on ice prior to centrifugation at 15,000 times the force of gravity for 20 minutes. The supernatant was filtered through 0.22 micron cellulose acetate filters and stored at -80°C until use. The amount of trypsin activity in the fecal extracts ranged from 0.4-402 μg/ml (n=19) as measured by the ability of the sample to hydrolyze a fluorescently-labeled trypsin peptide substrate (Boc-Gln-Ala-Arg-AMC HCl, BACHEM California, Incorporated, Torrance, CA). Total protease activity was measured as the ability of the sample to hydrolyze a fluorescent dye-labeled casein substrate (EnzChek Protease Assay Kit (E-6639), Molecular Probes, Eugene, OR). Irritation induced in the EPIDERM skin culture correlated with the total protease as well as trypsin activities of the fecal extracts. Based on the literature sources as well as internal data, a trypsin-chymotrypsin insult was chosen as representative of a fecal insult, specifically a fecal protease insult, for the examples that follow.

The insult solution is prepared by diluting a 10 mg/ml stock solution in phosphate-buffered saline to a working concentration of 250 g/ml. The base of the stock solution is 50 mM NaOAcetate, pH 5.5 and 0.15 M NaCl stored at -80°C. One milliliter of the stock protease insult solution contains 2558 USP units of trypsin and 298 USP units of chymotrypsin and is available from Specialty Enzymes, Inc. of Chino, CA. The bile acid insult solution can be prepared by dissolving 65 mg of cholic acid, 62 mg of deoxycholic acid and 31 mg of chenodeoxycholic acid in 10 ml of phosphate-buffered saline. The bile acid insult components can be purchased from Sigma Chemical Co. of St. Louis, MO. Phosphate-buffered saline, pH 7.4 (hereinafter "PBS") can be purchased from Life Technologies of Rockville, MD.

After application of the insult solution, the well plates are incubated for six hours in the 37°C, 5% CO_2 incubator. At the end of six hours, the well plates are removed from the incubator, the underlying media is removed and stored at -80°C. The response of the EPIDERM skin culture to the test compositions/control and the insult solution is determined by measuring the amount of interleukin-1 alpha (referred to hereon as "IL-1 "). Interleukin-1 alpha can be quantified using an Interleukin-1 alpha Quantikine Kit available from R&D Systems of Minneapolis, Minnesota. Interleukin-1 alpha measurements are converted to Log_{10} for each of the treatments and the averages for each treatment are calculated. In order to determine the ability of the test compositions to reduce skin irritation caused by the biological insults, the percent mean reduction of IL-1 is calculated as follows:

$$\%\ \text{mean reduction of IL-1} = 100 \times \frac{\text{((PJ control + insult) result - (test composition + insult) result)}}{\text{((PJ control + insult) result - (PJ control + PBS) result)}}$$

(Test composition + insult) result = the measured amount of IL-1 from treatment with a test composition + insult.

(PJ control + insult) result = the measured amount of IL-1 from a treatment with a control formulation + insult.

(PJ control + PBS) result = the measured amount of IL-1 from a treatment with a control formulation with PBS.

The greater the % mean reduction of IL-1 , the more effective a composition is at reducing irritation caused by the biological insult (proteases or bile acids).

In order to insure that the test compositions/control do not affect the viability of the EPIDERM skin culture, a MTT assay is run. The MTT dye is taken up by the cells. The reduction of the dye as a result of cellular metabolism can be used to measure the cytotoxicity of the test compositions. In order to confirm viability, inserts of the EPIDERM skin culture that have already been subjected to the test compositions and biological insults are removed from their media and are washed consecutively through immersion in three different beakers of PBS. Fresh PBS is used for each test composition or control being evaluated. The PBS is discarded onto paper towel. The EPIDERM skin culture inserts are then patted onto paper towel and placed into the wells of a 24 well plate containing 300 microliters of pre-warmed media. After all of the EPIDERM skin culture inserts are washed, they are transferred to new 24 well plates containing 300 microliters of the MTT reagent. The MTT reagent is thiazolyl blue having the formula 3-[4,5-Dimethylthiazol-2-yl]-2,5-diphenyltetrzoliumbromide. The plates are incubated for 2 hours in a 37°C, 5% CO_2 incubator. After incubation, the EPIDERM skin culture inserts are transferred to 24 well plates and are immersed in 2 milliliters of MTT extraction buffer. The extraction buffer extracts the MTT reagent from the cells. The 24 well plates are parafilmed, covered and placed in ZIPLOCK bags to reduce evaporation of the extraction buffer. The covered plates are rocked overnight in the dark. Following overnight rocking, the liquid in the EPIDERM skin culture inserts is decanted back into the wells. The contents of each well are mixed and a 200 microliter aliquot is then removed from each well and transferred to a 96 well plate. The optical density (OD) of the samples is measured at 570 nm using a spectrophotometer. Five hundred seventy nanometers is the

optimal wavelength at which to measure the reduced form of MTT reagent. This reading is subtracted from a background reading at 650 nm to improve data quality. Percent viability of each test composition + insult relative to a negative petrolatum control + PBS is recorded as the Mean $OD_{\text{test composition + insult}}$ divided by the Mean $OD_{\text{PJ control + PBS}}$; the quotient then multiplied by 100.

EPIDERM skin culture studies were conducted to measure the reduction in IL-1 response between compositions of the invention and a fecal protease-induced irritation. The studies were conducted using polymers that are representative of the invention. The EPIDERM skin culture studies and associated MTT assays were conducted as already described herein and the results are as reported in Table 5. below.

Table 5.

Composition	Polymer Component of Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
A	2% AP-1-a	53% (5)	101%
B	2% AP-3	0% (5)	99%
C	1% AP-4	0% (5)	96%
D	6% AP-1-b	23% (5)	95%
E	6% AP-1-b with EMERSET 2452 emulsifier	27% (5)	108%
F	6% AP-1-b with ABIL EM90 emulsifier	0% (5)	98%

AP-1 = NARLEX DC-1 C_{12} alkyl polyacrylate polymer available from National Starch and Chemical Co. AP-1-a and AP-1-b have concentrations of 20% and 33%, respectively

AP-3 = ACULYN-R 33 polymer is a solution, 5% by weight, of partially crosslinked acrylate polymer available from Rohm and Haas.

AP-4 = RHEOTHIK 80-11 polymer is a solution, 10% by weight, of high molecular weight poly (sulfonic acid) polymer available from Cognis Corporation.

EMERSET 2452 is a low HLB surfactant. The make-up of the compositions in Table 5. is provided in Table 6. below.

Table 6.

Polymer	% Polymer Solution	% Petrolatum	% EMERSET 2452 surfactant	% ABIL EM90 emulsifier
2% AP-1-a	20%	80%	0%	0%
2% AP-3	20%	79%	1%	0%
1% AP-4	20%	79%	1%	0%
6% AP-1-b	20%	80%	0%	0%
6% AP-1-b EMERSET 2452	20%	79%	1%	0%
6% AP-1-b ABIL EM90	20%	79%	0%	1%

The IL-1 reduction results of Table 5. show that the compositions of the invention provide a skin protectant effect as evidenced by a reduced irritation response. Suppliers of the polymers provide the polymers as aqueous solutions. As seen by the results in Table 5., not all of the polymers tested showed activity with the EPIDERM skin culture test. Without intending to be bound by theory, it is believed that these polymers would reduce the irritation response of skin if they were delivered in a different formulation. The formulations tested may have interfered with the availability of negative charges at the surface of the polymer emulsion droplets. Similarly, it is believed that the surfactants/emulsifiers used could have interfered with the polymer emulsion interface.

The reduction of IL-1 results were analyzed to statistically identify "outlier" results. The EPIDERM skin culture is known to be variable with the variability attributed to differences in the culture, variation in the application of treatment and other uncontrollable factors. A statistical analysis technique was applied to identify when a result abnormally deviated from the rest of the data set. The irritation values were first converted to Log10 in order to make them more Gaussian (bell curve-shaped). After conversion, the values were analyzed for high or low value outliers; subsequently, the values were analyzed with a student's t-test to identify significant differences from the "control". The statistical analysis used to identify "outliers" is described on page 460 of the book, "Statistical Methods in Research and Production" edited by Owen L. Davies and Peter L. Goldsmith, published by Longman Group Limited, fourth revised edition published in 1984.

The compositions of the invention were also evaluated for their efficacy in a clinical study. The study was directed to measuring the erythema response to application of an "insult" and application of compositions of the invention. The control compositions were

100% petrolatum and 100% irritant mixture. The test compositions contained from 0.2% to 16.8% polymer; 0.8% preservatives/stabilizers including propyl paraben, methyl paraben, disodium EDTA, BHT and NaCl; and a balance of petrolatum. The panel size for the clinical study was a minimum of 17 adult males and females. The control and test compositions were applied to areas on the backs of the adults. Up to sixteen sites on each adult's back were used for the study. Each test site was 2.5 cm in diameter. The irritant mixture included trypsin, chymotrypsin and bile acid in phosphate-buffered saline at a total concentration of 1500 g/ml. The irritant mixture was either freshly prepared or refrigerated at -80°C and defrosted at 37°C just prior to use and then held in an ice bath. For each application of the irritant mixture, 0.2 ml of the irritant mixture was placed into a 25 mm HILLTOP chamber. Thirty milligram portions of the petrolatum control and test compositions were applied to the selected sites on each participant's back for twenty minutes. After application of the test compositions, the HILLTOP chambers with the irritant mixture were taped onto each test site and the petrolatum control site for 24 hrs.; an extra chamber was applied to a previously untreated site for 100% irritant mixture control. After 24 hrs., the HILLTOP chambers were removed. After an additional thirty minutes, experts evaluated the control and test sites for erythema, edema and dryness. The experts evaluated the sites using a scoring scale of 0 to 4 with 0.5 point intervals. The score given for each site was a combined evaluation for erythema, edema and dryness. The data recorded by the experts was analyzed using a Nonparametric Wilcoxon signed rank test statistical treatment to determine significant differences between two sites and, therefore, between two compositions. Each test site was treated with a particular composition and challenged daily with irritant mixture for up to ten days. When a test site reached a score of 2.5 or more, the test site was no longer treated or challenged. Participants returned daily (including weekends) for patch removal, evaluation and subsequent composition/irritant mixture application.

The lower the score, the more effective a composition was at preventing an irritation response. In Table 7. below, the irritation scores for four different NARLEX DC-1 polymer test compositions are provided for comparison with the scores for a petrolatum control and an irritant control. The NARLEX DC-1 polymer that was used contained 34% solids.

Table 7.

Number of Days After Application of Irritant Mixture	Petrolatum Control Site	Irritant Control Site	0.2% NARLEX DC-1 polymer Test Composition	1.7% NARLEX DC-1 polymer Test Composition	7.5% NARLEX DC-1 polymer Test Composition	16.8% NARLEX DC-1 polymer Test Composition
1	0.1	0.6	0.2 #	0.2 #	0.3 #	0.9 #
2	0.2	0.9	0.4	0.4	0.1 #	0.2 #
3	0.5	1.2	0.6	0.7	0.3 #	0.2 #
4	0.6	1.7	1.0 #	0.8 # *	0.5 #	0.6 #
5	1.4	1.9	1.5 #	1.3 #	1.0 #	1.4 #
6	1.7	2.1	1.6 #	1.6 #	1.0 # *	1.6 #
7	2.0	2.0	1.5 #	1.4 #	1.2 # *	1.7 #
8	2.0	2.0	1.5 #	1.6 #	1.1 # *	1.5 #
9	1.8	2.3	1.6 #	1.7 #	1.2 # *	1.5 #
10	1.9	2.4	1.8 #	1.7 #	1.5 # *	1.7 #

An asterisk ("*") after a value indicates a significant difference from the petrolatum control. A number sign ("#") after a value indicates a significant difference from the irritant control at a confidence level of 95%. The statistical analysis performed factored in the number of participants at any given time during the study. The number of participants varied between compositions because participants were dropped if their erythema scores reached the upper limit of 2.5. The irritation score results in Table 7. show that each of the NARLEX DC-1 polymer test compositions reduced skin irritation from day 1 of the study forward compared with the irritant control. Therefore, the compositions of the invention provide a benefit to skin that is exposed to biological insults such as fecal proteases and bile acids.

A second clinical study that was conducted also supports the efficacy of the compositions of the invention for reducing the irritation response of skin and for protecting the skin from irritants. Twelve healthy Caucasian participants were recruited who were between the ages of 18 and 60. Test areas were marked on the upper backs of the study participants. This study involved topical application of 30 l of test composition to the skin followed by patching with a protease/bile acid mixture in a 2.5 cm diameter HILLTOP chamber fitted with a pad. The proteases, trypsin and chymotrypsin (available from Specialty Enzymes and Biochemicals Co. of Chino, CA) were topically applied daily in the form of a patch having a concentration of 1500 g/ml plus bile acids to represent a repeated biological insult. The bile acid mixture included 6 mg/ml cholic acid sodium, 6 mg/ml deoxycholic acid sodium and 3 mg/ml chenodeoxycholic acid sodium, each in

phosphate-buffered saline (each acid is available from Sigma Chemical Company of St. Louis, MO). The phosphate-buffered saline had a pH of 7.4 (available from Life Technologies of Rockville, MD) and a control site to which only phosphate-buffered saline was applied was also included in the study.

When the HILLTOP chambers containing the treated pads were placed on the designated, randomized test sites on the upper backs of the test participants, the chambers were covered with SCANPOR semi-occlusive tape. The chambers remained in place overnight. During each daily visit, the chambers were removed and the underlying skin was allowed to air dry for 15-20 minutes. After the drying period, each test and control site was visually assessed in a blinded manner by an expert grader. The expert graders made the visual assessments under consistent lighting and the graders used a scoring system of 0 (no erythema) to 3 (severe erythema with edema and vesicles). If a visual score of greater than or equal 2 was observed for any test site, the site was no longer treated. Every day, the chambers were re-loaded with 200 L of fresh solution. The study was conducted for twelve days, Monday through Saturday (the chambers remained in place from Saturday to Monday).

Each study participant had four test sites on their upper back (including the saline and irritant controls): (1) Phosphate-buffered saline (pH=7.4); (2) Irritant mixture of 1500 g/ml trypsin/chymotrypsin + bile acids; (3) Petrolatum "control" (containing 98.17% petrolatum; 1.68% ABIL EM90 emulsifier; and 0.15% propylparaben); and (4) Petrolatum plus polymer (containing 82.17% petrolatum; 16% NARLEX DC-1; 1.68% ABIL EM90 emulsifier; and 0.15% propylparaben). The petrolatum used in compositions "3" and "4" was sourced from Ultrapure Chemical, Inc.; the ABIL EM90 emulsifier was sourced from the Goldschmidt Chemical Company; and the propylparaben was sourced from Protameen Chemicals. The cumulative irritation scores are reported for each of the four sites in Table 8. below. The cumulative irritation scores are based on the highest erythema value obtained for a site; for example, if a site reached a score of 2 and was discontinued, but had a score of 3 on the following day, the score of 3 was used for the cumulative calculation.

Table 8.

Test Site	Cumulative Irritation Score
Phosphate-buffered saline site	80
Irritant Mixture	216
Petrolatum + emulsifier	134
Petrolatum + polymer + emulsifier	102.5

Using the mean score values reported in Table 9. below, the data was analyzed using ANOVA statistical analysis. The analysis showed that the Petrolatum + polymer + emulsifier sites had significantly lower erythema than the Irritant Mixture sites and the Petrolatum + emulsifier sites. Therefore, these clinical study results support the efficacy of the compositions of the inventions for reducing the irritation response of the skin and for protecting the skin from irritants.

Table 9.

Test Site	Mean Irritation Score
Phosphate-buffered saline site	0.67
Irritant Mixture	1.8
Petrolatum + emulsifier	1.1
Petrolatum + polymer + emulsifier	0.85

In order to demonstrate that compositions of the invention do indeed transfer from the liner or other bodyfacing material of an absorbent article, studies were conducted to quantify the amount of composition transferred from the liner of a diaper to a TEGADERM skin patch. The studies were conducted on infants wearing a "Size 3" HUGGIES diaper fitting a child ranging in weight from about 16 to about 28 pounds. The children participating in the studies wore the test diapers for a period of 6 hours; therefore, the amount of composition transferred to a TEGADERM skin patch over a period of 6 hours was measured. The children were first evaluated for any type of diaper rash or skin irritation and, if such irritation was present, those children did not participate. Prior to application of the diapers being evaluated in the studies, each participating child's buttocks were wiped with a HUGGIES NATURAL CARE unscented wet wipe. A 1.75 square inch TEGADERM adhesive skin patch was then applied to each participating child's buttocks in such a way that the entire skin patch would be in contact with the bodyfacing surface of the bodyside liner of the diaper. Next, a disposable diaper having a composition of the invention on the bodyfacing surface of the bodyside liner was applied to each child. The children wore the test diapers for six hours, however, between the three and 4 hour time points, the children's' caregivers changed their diapers and applied a new test diaper. After six hours, the diapers and the TEGADERM skin patches were removed. The TEGADERM skin patches were removed by first lifting up one corner of the patch and then gently pulling back the patch to remove. The skin patches were placed in individual vials using tweezers to avoid contamination. The skin patches were then analyzed for the amount of composition taken up from the bodyside liners of the diapers. The amount of